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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,968	02/13/2002	Heinrich Wieland	70301/56970	6225
21874	7590	01/03/2007	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			HANLEY, SUSAN MARIE	
		ART UNIT	PAPER NUMBER	
		1651		

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/049,968	WIELAND ET AL.	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 20 September 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 54-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 54-69 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.

- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application
 6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/20/06 has been entered.

Claims 54-69 are pending.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

Claims 54-56, 58, 59, 61-64 and 67 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-7 of U.S. Patent No. 6,071,526.

Applicant argues that claims 27-31, 34 and 38 have been cancelled and the newly added claims 54-69 have a scope of invention that is believed to be different than claims 2-7 of the '526 patent.

Applicant's argument regarding the allegedly different scope of the newly added claims has been considered but is not found persuasive. Applicant has not supported why the newly added claims are thought to have a sufficiently different scope from the cancelled claims such that there is no overlapping subject material with the '526 patent. On the contrary, the newly added claims are simply a consolidation of the canceled claims. New claims 54 and 56 correspond to the combination of cancelled claims 27-29 which are drawn to increasing, stabilizing or restoring collagen by the administration of an aromatase inhibitor or an anti-estrogen. New claims 61-64 correspond to cancelled claims 30 and 31 regarding the nature of the sterol inhibitor that can be a soya glycine sterol. New claim 55, drawn to topical

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administration, corresponds to canceled claim 53. Hence, the scope of the newly added claims is the same as the indicated cancelled claims, which in turn are obvious over claims 2-7 of the '526 patent. Applicant has not responded to the content of the rejection.

New claims 58 and 59, drawn to the effects of the inhibitor on aromatase activity or the effect of dihydrotestosterone, are obvious over claims 2-7 of '526 because the practice of claims 2-7 of '526 would naturally result in the effects of instant claims 58 and 59.

New Rejections

Claim Rejections - 35 USC § 102

Claims 54-69 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schmidt et al. (WO 97/36570; item BG in the IDS filed 10/8/02).

Schmidt et al. disclose a method of administering a topical formation of a substance to treat disorders of the subcutaneous connective fatty tissue, such as cellulite, to improve the appearance of a body region having cellulite (abstract). The composition comprises at least one aromatase inhibitor, as in instant claim 54, and optionally, an anti-estrogen, as in instant claims 56. Schmidt teaches suitable anti-estrogen compounds on p. 8, lines 15-25. A listing of aromatase inhibitors is disclosed on p. 6, lines 18-34. For example, the aromatase inhibitor can be 4-hydroxyandrostenedione (Formestan, p. 6, line 19). The compound 4-hydroxyandrostenedione is also inherently a 5-alpha reductase inhibitor and would therefore inhibit the production of dihydrotestosterone, as required by instant claims 57-61. Schmidt also teaches that soya-glycine is a suitable inhibitor of aromatase for the disclosed treatment method (p. 7, lines 20-35). Optionally, the soya-glycine can be in an oxidized form (p. 8, lines 1-13), as in instant claims 61-64. The composition can be applied topically for treatment of a local area (p. 9, lines 1-5). The composition can be formulated as a cream, emulsion or gel, as in instant claim 66. The composition comprises between about 0.001 and about 5% of the aromatase inhibitor (p. 10, lines 30-35), as in instant claim 65.

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Schmidt et al. did not teach that the estrogen inhibitor has the claimed effects on collagen which aid in its pharmacological effect for the purpose of improving the appearance of a body region. However, these claimed effects do not make the instant claims patentable over the prior art because the estrogen inhibitor's effects on collagen is an inherent property of the compound.

MPEP 2112.02: PROCESS CLAIMS — PRIOR ART DEVICE ANTICIPATES A CLAIMED PROCESS IF THE DEVICE CARRIES OUT THE PROCESS DURING

Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986) See also *In re Best*, 562F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993). Further, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

The disclosure of Schmidt et al. also meets the limitation of claims 67-69 because applying the claimed substance to the skin would inherently impart some of the substance to collagen in the skin. Thus, the estrogen-inhibiting effects of the substance would stabilize collagen in the skin while also treating cellulite. The disclosure meets the limitations regarding wrinkles, strias and atony because cellulite causes the skin to lose tonality and appeared wrinkled. The disclosure meets the limitations of claim 69 because exposure to the sun is a cause of wrinkles or loss of skin tone and the application of the disclosed composition will naturally treat this.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Leon B. Lankford, Jr.
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